13-1286

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

ALLERGAN, INC., and DUKE UNIVERSITY,

Plaintiffs-Appellees,

—and—

MURRAY A. JOHNSTONE, M.D.,

Plaintiff,

—v.—

ATHENA COSMETICS, INC.,

Defendant-Appellant,

—and—

PHARMA TECH INTERNATIONAL, INC., PRODUCT INNOVATIONS, LLC, NORTHWEST COSMETIC LABORATORIES, LLC, and R & G BUSINESS LLC,

Defendants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
CONSOLIDATED NOS. 07-CV-1316 AND 09-CV-0328
JUDGE JAMES V. SELNA

REPLY BRIEF OF DEFENDANT-APPELLANT ATHENA COSMETICS, INC. [NON-CONFIDENTIAL]

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CERTIFICATE OF INTEREST

Counsel for the defendant-appellant certifies the following:

1. The full name of every party or amicus represented by me is:

Athena Cosmetics, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is: NONE

3. All parent corporations and any publicly held companies that own 10 percent one more of the stock of the party or amicus curiae represented by me are: NONE

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

In Trial Court: Katten Muchin Rosenman LLP (Kristin L. Holland, Breighanne A. Eggert, Christine E. Bestor, Craig M. Kuchii, David A. Kettel, Elese E. Hanson, Jeremy C. Daniel, Kimberly A. Beis, Martin S. Masar III, Pamela Tsao, Robert B. Breisblatt, Stephen P. Benson); Graves and Walton LLP, a/k/a Graves & Shaw LLP, a/k/a Graves Law Firm PC (Adrian Li, James Woo Ahn, John R. Walton, Philip J. Graves, Shen Li Khong); Jeffer Mangels Butler & Mitchell LLP (Elizabeth Ann Culley); Russ August and Kabat (Fredericka Ung); Snell & Wilmer LLP (Greer N. Shaw); Morgan Lewis & Bockius LLP (Monique E. Cho); Toberoff & Associates PC (Pablo D. Arredondo)

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CONFIDENTIAL MATERIAL OMITTED

The material omitted on page 16 describes communications within Athena regarding potential marketing campaigns; the material omitted on page 19 describes Allergan's correspondence with FDA regarding prescription and non-prescription eyelash products; and the material omitted on page 23 describes information gathered by both Allergan and Athena regarding the market for eyelash products.

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INTRODUCTION

In *Goldsmith v. Allergan, Inc.*, 2011 U.S. Dist. LEXIS 6233 (C.D. Cal. Jan. 13, 2011), Allergan escaped liability for off-label promotion of its drug Botox by convincing the court that the plaintiff's claim under California law was impliedly preempted by the FDCA. Allergan successfully argued that a state-law claim is preempted if it is "***in substance (even if not in form) a claim for violating the FDCA***"—*i.e.*, if "the state claim would not exist if the FDCA did not exist." Contrary to what it says now, Allergan told the *Goldsmith* court that the preemption "bar is ***not limited to actions that expressly seek to enforce the FDCA***. Rather, a plaintiff may not use state unfair competition laws as a vehicle to bring a private cause of action that is ***based on*** violations of the FDCA." Allergan Br. in Support of Mot. to Dismiss (Dkt. No. 80-1), No. 2:09-cv-07088-PSG-E (C.D. Cal. Nov. 19, 2010) ("Goldsmith Br.") at 6 (emphases added). Athena featured these admissions in its opening brief, and showed that Allergan is judicially estopped from arguing the opposite position in this Court.

In response, Allergan devotes precisely one sentence to *Goldsmith*, and buries that reference in an obscure footnote on page 22 of its 60-page opposition. Allergan dismisses *Goldsmith* as "irrelevant" because the plaintiff in that case premised his UCL claim "on a violation of the FDCA—not a claim of unlawfulness predicated on a violation of California's Health and Safety Code."

This is gibberish, and it cannot be squared with Allergan's assertions in *Goldsmith*. Allergan seeks here to "use state unfair competition law" to enforce FDCA requirements that, through state enactments, are incorporated into California law. Allergan's claim is thus "in substance (even if not in form) a claim for violating the FDCA," and is therefore preempted. Both judicial estoppel and federal preemption bar Allergan's claim.

Allergan's other arguments fare no better. In defending the district court's summary-judgment ruling, Allergan pretends that a trial took place, and that its task on appeal is to show that the record contains *some* proof to support the decision below. But that is not the applicable standard. The evidence cited by the district court and Allergan is contradicted (indeed, far-outweighed) by an abundance of proof that RLA was a lawful cosmetic. And Allergan's attempt to justify the district court's unprecedented injunction—which bars Athena from engaging in a wide range of indisputably lawful conduct—stands decades of controlling jurisprudence on its head.

In the end, Allergan cannot escape the shackles it forged with its own hand. Its claim is preempted, and it is estopped from arguing otherwise. The judgment below must be reversed.

I. ALLERGAN'S CLAIM IS PREEMPTED

In our opening brief, we showed that Congress deliberately chose to vest a single federal agency—FDA—with sole authority to enforce the FDCA, and that this enforcement scheme preempts state-law claims that seek to privately police alleged violations. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Allergan ***never responds to this showing***. Instead it makes a variety of arguments that are either impertinent to the issues in this case or wrong as a matter of law.

A. Allergan's Distractions

Allergan begins its argument by invoking a so-called "assumption against preemption," and asserts that a state-law claim cannot be preempted unless "Congress has unmistakably ordained" that result. (Allergan's Opposition Brief ("AllBr.") 16) In fact, in enacting the FDCA, Congress left "no doubt that it is the Federal Government rather than private litigants" that is "authorized to file suit for noncompliance." *Buckman*, 531 U.S. at 349 n.4 (citing 21 U.S.C. § 337(a)).

In any event, the Supreme Court has made clear that the "assumption against preemption" applies only in circumstances where the state-law claim at issue lies at the core of the "historic police powers of the States." *Arizona v. Inter Tribal Council of Ariz., Inc.*, 2013 U.S. LEXIS 4544, at *20-21 (June 17, 2013). Where the claim is *not* grounded on "traditional state law tort principles"—such as

remedying deception or infliction of bodily harm—no negative presumption applies. *See Buckman*, 531 U.S. at 347-48, 352.

Allergan concedes that its UCL claim was premised on "a pure statutory violation" of a California law that "borrows" FDCA requirements against selling drugs for which regulatory approval has not been sought. (AllBr. 19, 21) "[A]sking for FDA's [authorization]…is not a matter of state-law concern." *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2581 (2011). "Accordingly—and in contrast to situations implicating…the historic primacy of state regulation of matters of health and safety—no presumption against pre-emption obtains in this case." *Buckman*, 531 U.S. at 348.[1]

Allergan also goes to great lengths to show that it would not be *impossible* for Athena to comply with both federal and California law by seeking regulatory approval for its products. (AllBr. 26-27) This is a classic straw-man argument: Athena does not rely on "impossibility" preemption. Implied conflict preemption arises *either* "when compliance with both federal and state regulations is

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[1] In a similar vein, Allergan argues that "'when faced with a potential conflict' between federal and state law, '[c]ourts try to give as much effect to both statutes as possible.'" (AllBr. 23 (quoting *POM Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170, 1175 (9th Cir. 2012).) But *POM Wonderful* involved a potential clash between two *federal* statutes—the FDCA and the Lanham Act—*not* a conflict between federal and state law. In the latter scenario, the Supremacy Clause places federal law in a privileged position. *See Mensing*, 131 S. Ct. at 2580-81 (Supremacy Clause means "courts should not strain to find ways to reconcile federal law with seemingly conflicting state law").

impossible [impossibility preemption] *or* when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress [obstacle preemption]." *Hillman v. Maretta*, 133 S.Ct. 1943, 1950 (2013) (emphasis added). It is the latter form of preemption that bars Allergan's claim.

In perhaps its most egregious attempt at misdirection, Allergan proclaims that Athena's implied preemption argument is undermined by "Congress's express statement in the FDCA that states may enact and enforce parallel state laws…." (AllBr. 16) The statutory provision Allergan cites in support of this argument, however, is inapplicable here. Specifically, Allergan cites the Drug Amendments of 1962, which "amended the FDCA [to] shift[] the burden of proof" in vetting a new drug "from the FDA to the manufacturer." *Wyeth v. Levine*, 555 U.S. 555, 567 (2009). The language Allergan points to states: "[n]othing *in the amendments made by this Act* to the [FDCA] shall be construed as invalidating any provision of State law which would be valid in the absence *of such amendments* unless there is a direct and positive conflict…." (AllBr. 17 (emphases added))

Athena's preemption argument is not based on the Drug Amendments of 1962. Rather, Allergan's claim is preempted because it contradicts Congress's decision to give FDA sole authority to enforce FDCA requirements. This exclusive-enforcement provision has been part of the FDCA since its enactment.

See Pub. L. No. 717, 52 Stat. 675, § 307 (June 25, 1938). Allergan's reliance on the Drug Amendments of 1962 is thus entirely misplaced.

B. Allergan's Claim Is Preempted Under *Buckman* and Its Progeny

Allergan's claim is impliedly preempted because, like the state-law claim in *Buckman*, it interferes with Congress's objective of ensuring that all actions to enforce FDCA requirements are brought by FDA. Allergan tries to distinguish *Buckman* in two ways, but neither is viable.

First, Allergan asserts that "*Buckman* involved medical devices, and the FDCA contains an express preemption provision relating to those devices' regulation." (AllBr. 24) But *Buckman*'s holding in no way depended on FDCA's device-specific preemption clause; it rested on the exclusive enforcement provision in 21 U.S.C. § 337(a), which applies to all products under FDA's jurisdiction. Indeed, the Court made clear that the express-preemption provision Allergan cites had no bearing on its implied-preemption analysis. *See* 531 U.S. at 352.

Second, Allergan argues that whereas *Buckman* involved a claim "based wholly on dealings with the FDA," the claim here is grounded solely on California's Sherman Law—which incorporates FDCA requirements wholesale into state law. (AllBr. 25) This is a non-sequitur: whether Athena's alleged duty to seek FDA approval arises under (1) the FDCA itself or (2) a state law that "borrows" FDCA requirements, it is inescapably a claim about "dealings with the

FDA." Indeed, just like Allergan, the *Buckman* plaintiffs purported to base their claims exclusively on state law. 531 U.S. at 343, 347-48. That made no difference; the claim was preempted because it was grounded upon alleged misrepresentations to, or "dealings with," FDA.

Allergan argues that its state-law claim does not necessarily implicate Athena's dealings with FDA, because California's Sherman Law allows new drugs to be approved by either FDA or California's State Department of Health Services ("CSDHS"). (AllBr. 20 & n.2) But the evidence was unchallenged below—and Allergan does not dispute here—that CSDHS has *never* approved a New Drug Application ("NDA"), has *no* institutional capacity to do so, and *uniformly* defers to FDA's decisions on NDAs. That California law theoretically permits CSDHS to approve an NDA cannot defeat preemption. *See Jones v. Rath Packing Co.*, 430 U.S. 519, 526 (1977) (obstacle preemption "requires [courts] to consider the relationship between state and federal laws as they are interpreted and applied, not merely as they are written").

Aside from pointing to meaningless distinctions, Allergan attempts to square its claim with the holding of *Buckman* by insisting that California's Sherman Law "furthers" Congress's purposes in enacting the FDCA: "to advance consumer safety" and "to protect consumers from dangerous products." (AllBr. 27) This superficial argument has repeatedly been rejected by the Supreme Court. *See Gade*

v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 103 (1992) ("In determining whether state law 'stands as an obstacle' to the full implementation of a federal law, it is not enough to say that the ultimate goal of both federal and state law is the same."); *Int'l Paper Co. v. Ouelette*, 479 U.S. 481, 494 (1987) ("it is not enough to say that the ultimate goal of both federal and state law is to eliminate water pollution").

Allergan also makes the policy argument that FDA is "too overburdened to take action," and requires the assistance of private litigants. (AllBr. 1, 27) The Supreme Court has rejected this argument as well. *See Astra USA, Inc. v. Santa Clara Cnty.*, 131 S. Ct. 1342, 1350 (2011) (fact that responsible agency "lack[ed]" sufficient "oversight mechanisms" was irrelevant, as "Congress did not respond to the reports of inadequate [agency] enforcement by inviting [private] entities to launch lawsuits in district courts across the country"); *see also Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555, 561 (9th Cir. 1995) ("[T]he performance of an expert regulatory agency…is irrelevant to the preemption analysis.").

C. Judicial Estoppel Bars Allergan's Claim

Allergan's arguments contradict not only *Buckman*, but numerous cases that have followed it—including the Ninth Circuit's recent decisions in *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010), and *Perez v. Nidek Co.*, 711 F.3d 1109

(9th Cir. 2013).[2] But there is no clearer refutation of Allergan's argument than Allergan's own assertions in *Goldsmith*. As detailed above, Allergan moved to dismiss that case on preemption grounds, arguing that a plaintiff may not "'shoehorn' claims based on alleged FDCA violations into state consumer fraud causes of action." Goldsmith Br. 1. The plaintiff responded—as Allergan does here—that he was doing no such thing, and that "using a state law to directly enforce the FDCA is *vastly different* than using that law to enforce a *state remedy* which may nevertheless be identical to the FDCA." Brief in Opposition (*Goldsmith* Dkt. No. 81) at 5 n.3 (emphasis added).

In reply, Allergan dismissed this argument as "pure sophistry," a "distinction without a difference," and "a desperate attempt to avoid the clear law" of preemption. Allergan Reply Br. (*Goldsmith* Dkt. No. 82) at 11. "Whether Plaintiff [was] enforcing 'a decision by the FDA'" as incorporated into California law "or the FDCA itself," Allergan argued, his state-law claim was "nothing but an impermissible attempt to privately enforce the FDCA." *Id.* The court agreed, and

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[2] Allergan's attempts to distinguish these cases are unavailing. Allergan notes that *PhotoMedex* "primarily" involved a claim under the federal Lanham Act (AllBr. 19), but does not dispute that the Ninth Circuit rejected the state-law claim on the same reasoning. And Allergan admits that the claim in *Perez* was preempted because it existed "solely by virtue of the FDCA" (AllBr. 25)—precisely the situation here.

held plaintiff's claim for alleged "violations of the FDCA" preempted. 2011 U.S. Dist. LEXIS 6233, at *6.

Allergan's assertions in *Goldsmith* were correct, and Allergan prevailed because of them. Allergan is therefore estopped from espousing a contrary view in this Court. *Baughman v. Walt Disney World Co.*, 685 F.3d 1131, 1133 (9th Cir. 2012) (successful litigant may not change positions "simply because his interests have changed"); *see Speedtrack, Inc. v. Endeca Techs., Inc.*, 2013 U.S. App. LEXIS 7551, at *14 (Fed. Cir. Apr. 16, 2013) ("Courts invoke judicial estoppel…to 'protect against a litigant playing fast and loose with the courts.'") (quoting *Russell v. Rolfs*, 893 F.2d 1033, 1037 (9th Cir. 1990)).

D. California's Sherman Law Does Not Provide an End-Run Around Preemption

At bottom, Allergan's case boils down to the untenable proposition that, unlike the plaintiffs in all the cases it tries to distinguish, Allergan was clever enough to invoke California's Sherman Law in addition to the UCL, and should escape preemption for that reason. There is no merit to this argument.

California's UCL purports to authorize anyone who has lost money or property on account of an "unlawful" practice to bring an action for redress. *See* Cal. Bus. & Prof. Code § 17200. The statute "borrows" other laws—state *and federal*—to determine when a practice is "unlawful" in California. *Davis v. HSBC Bank Nev., N.A.*, 691 F.3d 1152, 1168 (9th Cir. 2012). However, when the

borrowed law is a federal statute (such as the FDCA) enforceable only by the responsible federal agency, a UCL claim is preempted whenever it would exert an extraneous pull on the uniform enforcement scheme enacted by Congress. *See In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1290-91 (C.D. Cal. 2008) (private parties cannot use "state unfair competition law[] as a vehicle to bring a private cause of action that is based on violations of the FDCA"). That is what Allergan argued in *Goldsmith*, and it is indisputably correct.

Allergan insists that this case is different, however, because its UCL claim borrows not directly from the FDCA, but from California's Sherman Law, which in turn borrows from or "incorporates" FDCA requirements into state law. According to Allergan, this makes all the difference in the world, for "Allergan sued *only* under state law (the UCL) to remedy violations of state law (the Sherman Law)" (AllBr. 19), and "did not allege—and has never alleged—any specific violations of the FDCA." (AllBr. 10)

As a threshold matter, these assertions are wishful thinking on Allergan's part: its complaint was, in fact, rife with allegations of "specific violations of the FDCA." *See* A3398 ("In violation of federal…laws regulating the manufacture and sale of prescription medicines, [Athena is] manufacturing and selling [RLA] without FDA approval"); A3400 (Athena has acted "in violation of…federal

misbranding laws"); *id*. (RLA "constitute[s] [a] 'drug[]' under…federal law" (citing 21 U.S.C. § 231(g)(1), 21 C.F.R. § 310.527(a)); A3402 (RLA "constitute[s] [a] 'new drug[]' pursuant to…federal law, namely…21 U.S.C. § 321(p)(1) and 21 C.F.R. § 310.527(a)"); *id*. (Athena has "fail[ed] to comply with…federal misbranding regulations—specifically…21 C.F.R. § 310.527"). But even if Allergan (and the district court) had managed to cite only the Sherman Law and avoid mention of the FDCA, Allergan's argument would fail.

As the Supreme Court has explained, the fact that "a local court…may purport to apply legal rules identical to those prescribed in [a] federal Act…does not mean that all relevant potential for debilitating conflict is absent." *Amalgamated Ass'n of St., Elec. Ry. & Motor Coach Employees v. Lockridge*, 403 U.S. 274, 288-89 (1971). As recently as this Term, the Court reiterated that "[p]re-emption is not a matter of semantics….[A] proper [preemption] analysis requires consideration of what the state law in fact does…." *Wos. v. E. M. A.*, 133 S. Ct. 1391, 1398 (2013). Thus, "distinguishing between pre-empted and non-pre-empted claims based on the particular label affixed to them would elevate form over substance" and improperly "allow parties to evade" preemption. *Aetna Health Inc. v. Davila*, 542 U.S. 200, 214 (2004); *see also Mich. Canners & Freezers Ass'n v. Ag. Mktg. & Bargaining Bd.*, 467 U.S. 461, 478 (1984) (finding preemption where "[i]n practical effect," state law "impose[d]…the same

[consequences] with which Congress was concerned in enacting" the federal statute); *Chicago & Nw. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 324 (1981) (noting that preemption "cannot be avoided by mere artful pleading" and finding preemption where state-law claim "represent[ed] little more than an attempt…to gain from [state] courts [] relief [that] was denied by" responsible federal agency).

However Allergan dresses up its case, the *conduct* it addresses is Athena's alleged failure to secure FDA approval—just as the conduct in *Buckman* was alleged false statements to FDA. In these circumstances, it makes no difference whether the complaint seeks to use only the California UCL to "borrow" FDCA requirements, or also the Sherman Law to "incorporate" the very same requirements into California law. Either way, the claim is "in substance (even if not in form) a claim for violating the FDCA," and is preempted. *Loreto v. Procter & Gamble*, 2013 U.S. App. LEXIS 3813, at *5 (6th Cir. Feb. 22, 2013).[3]

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[3] Allergan relies on *Farm Raised Salmon Cases*, 175 P.3d 1170 (2008), and urges this Court to follow that decision so as to avoid "creating a direct conflict with the California Supreme Court…." (AllBr. 23) As explained in our opening brief, state-law decisions have no binding effect on questions of federal preemption, and the case is distinguishable in any event. As Allergan admits, *Salmon* involved "deceptive marketing practices" (AllBr. 21)—a subject traditionally subject to state regulation—not a "pure statutory violation" of FDCA requirements, such as the one alleged here. The same is true of the three unpublished district-court cases Allergan cites that followed *Salmon*: each

II. THE GRANT OF SUMMARY JUDGMENT WAS IMPROPER

Even if Allergan's claim were not preempted, the ruling below could not stand.

A. Material Facts Were Disputed

In granting summary judgment, the district court resolved multiple factual disputes in favor of Allergan and drew numerous inferences against Athena. To justify that outcome, the court embraced a fiction that Athena "conceded" that its products were drugs, and deemed disputed facts "uncontroverted." Allergan makes no attempt to defend the district court's peculiar suggestion that Athena conceded the central issue in the case. But like the court below, Allergan asserts that the record contained "uncontroverted evidence" that, *inter alia*, Athena created its products to grow eyelashes, and labeled and marketed them for that purpose. (AllBr. 33)

These points were not uncontroverted. As our opening brief recounted, the evidence showed that Athena's founder always intended the company's products to be sold as cosmetics. (A693) Less than a year after entering the market, Athena updated its labeling and advertising to clarify that its products are intended solely to enhance the beauty and appearance of eyelashes, then contractually prohibited

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alleged "false and misleading" statements that deceived consumers, not pure statutory violations.

its authorized resellers from making drug claims. (A699, 1116) FDA subsequently scrutinized numerous eyelash products and concluded that some manufacturers had made improper "growth" claims, but not Athena. (A1033, 1036-38)

Allergan argues that the facts favoring Athena were "contradicted by the record." (AllBr. 34) But the question on summary judgment is not whether one party's proof "will ultimately be found convincing or persuasive." The "only" question is "whether the parties have proof for their claims and defenses such that a trial is needed." 11 Moore's Federal Practice § 56.02[2] (Matthew Bender 3d ed.). The summary-judgment ruling wrongly deprived Athena of the right to present its case to the trier-of-fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986) ("Rule 56 must be construed with due regard…for the rights of persons asserting…defenses that are adequately based in fact to have those…defenses tried[.]").

B. The District Court Drew Inferences Against Athena

In addition to improperly resolving disputes, the district court drew inferences against Athena based on Allergan's biased rendition of the facts. Apparently hoping for similar treatment in this Court, Allergan litters its opposition with factual distortions and, in some instances, sleight of hand.

For example, Allergan repeatedly quotes statements about eyelash "growth" made by *unauthorized* resellers of Athena's products. (AllBr. 36-37) In an attempt to impute these rogue statements to Athena, Allergan quotes the declaration of a "reseller" that "all content…on [her] website [is] approved by Athena." (AllBr. 34) The clear implication of Allergan's telling is that Athena actually approved the unauthorized "growth" claims. But that simply is not true. Athena does not control or condone the statements made by unauthorized resellers, and the "reseller" who stated that Athena pre-approved her website was an *authorized* reseller that never made any claims regarding eyelash growth.[4] (A1127-33)

Allergan also relies on *draft* promotional materials and *proposed* advertising that Athena rejected, and no consumer ever saw [redacted] (AllBr. 9, A892-93) The fact that

[4] Allergan incorrectly asserts that Athena waived any argument that its objective intent should not be determined by the statements of unauthorized resellers. (AllBr. 34) In fact, Athena argued forcefully in opposition to summary judgment that such statements are irrelevant to RLA's intended use, and cannot override Athena's approved labeling and marketing. (A1513-14)

Athena *rejected* these ideas is far more indicative of its objective intent than the cherry-picked statements cited by Allergan.

By crediting Allergan's overzealous advocacy and drawing disputed inferences against Athena, the district court committed reversible error. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) ("[on] summary judgment the inferences to be drawn from the underlying facts…must be viewed in the light most favorable to the [opposing] party").

C. The Court Ignored Proof Exonerating Athena

In accepting Allergan's one-sided rendition, the district court disregarded critical evidence supporting Athena's position. In particular, the court paid no heed to Athena's showing that RLA was labeled and advertised strictly as a cosmetic, and that FDA made an apparent determination to that effect.

When deciding whether a product is a drug or cosmetic, courts have long recognized that statements on product labels are paramount. (Athena's Opening Brief ("AthBr.") 42-46) Since at least 2007, Athena's labels have made only cosmetic claims. Allergan does not deny that the court below discounted Athena's labeling. Rather, it asserts that other courts have similarly declined to credit "disclaimers" that products are not drugs. (AllBr. 35-36)

But Athena's labels are not "disclaimers"—they are consumers' main source of information about the products' intended uses. The cases cited by Allergan

make precisely this point. For example, in *United States v. Kasz*, the court deemed the defendant's product a drug based on "labeling" that said the product cured baldness. 855 F. Supp. 534, 538 (D.R.I. 1994). Overt drug claims on the product's label trumped "disclaimer language" that appeared only in "some…promotional material." *Id.* at 542; *see also United States v. Millpax*, 313 F.2d 152 (7th Cir. 1963) (disclaimer in "form letter" did not negate statements made at point of purchase that product cured cancer).[5] What these cases teach is that courts may not disregard product labels, and instead glean a manufacturer's objective intent solely from isolated statements in collateral marketing materials. Yet that is exactly what the district court did.

The district court also rejected powerful proof that FDA reviewed Athena's labeling and concluded that RLA was a lawful cosmetic. Allergan argues that the court was right to disregard this showing because agency "inaction" deserves no evidentiary weight, especially when FDA has "over 8 billion" products to police. (AllBr. 42-43) But this is not a situation where FDA has deemed the relevant subject matter unworthy of attention. Between 2007 and 2011, FDA gave careful consideration to the proper classification of eyelash products and scrutinized the

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[5] Allergan's reliance on *United States v. Storage Spaces…"49"*, 777 F.2d 1363 (9th Cir. 1985), is entirely misplaced. The issue in that case was whether the government had probable cause to conduct a search for misbranded drugs. The court found that the presence of a disclaimer on the defendant's product did not invalidate the government's warrant.

labeling of numerous conditioners, specifically to "assess[] whether any such eyelash products are drugs" under the FDCA. (A2834) FDA determined that some of Athena's competitors were making improper drug claims. But [redacted] FDA took no issue with Athena's labeling.

Allergan asserts that FDA might well "believe a violation of law has occurred," but has simply not gotten around to challenging Athena's conduct. (AllBr. 42) [redacted] (A2879) FDA's apparent determination that Athena's products are lawful cosmetics, therefore, is not "rampant speculation," as Allergan contends. (AllBr. 43) It is the most reasonable inference a trier-of-fact could draw.

Should its claim survive preemption, Allergan will be free to argue at trial that Athena's labeling and FDA's actions are outweighed by other evidence of Athena's supposed intent. The district court was not free, however, to make this determination on summary judgment.

D. The District Court Misapplied the Intended Use Standard

Not only did the district court make improper factual findings, it misapplied the law on how a product's "intended use" is determined. Allergan argues that a

manufacturer's subjective intent, historical advertising and a product's physical properties are all potentially "relevant" considerations. (AllBr. 37-44) But the district court did not merely *consider* these factors—it treated them as dispositive.

As noted above, a product's intended use is determined primarily from its labeling and advertising. (AthBr. 43-44) Allergan notes that courts occasionally have looked to additional factors as *corroborative* evidence of objective intent.[6] (AllBr. 31-32) No court, however, has held that such factors can *override* the objective intent manifested by a product's labeling. To the contrary, when product labels have made no drug claims, courts have rejected attempts to classify them as drugs based on tangential factors. *See Nat'l Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 335 (2d Cir. 1977) (rejecting drug classification based on physical properties of high-dose vitamins and evidence that consumers use them for medicinal purposes); *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155,

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[6] Even the cases cited by Allergan recognize that objective intent turns on labeling and advertising. *See United States v. Regenerative Scis., LLC*, 878 F. Supp. 2d 248, 256 (D.D.C. 2012) (objective intent determined by statements on manufacturer's website); *United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547, 567-69 (D.N.J. 2004) (objective intent determined by "the labels, websites, articles and other marketing material…distributed by" defendant); *United States v. 22…Finished Devices*, 714 F. Supp. 1159, 1165 (D. Utah 1989) ("defendants' labeling and advertising" demonstrated objective intent "to treat, prevent, mitigate, or cure disease").

163 (4th Cir. 1998) (rejecting drug classification based on effects of cigarettes on the structure and function of the body).[7]

Finally, Allergan questions how RLA can enhance the appearance of eyelashes without actually causing them to grow. (AllBr. 43-44) This argument just exposes another fundamental misunderstanding of the intended use standard that was embraced by the district court. "Whether or not a product is a drug" does "not" depend "on the physical properties of the product or what effect the product has on humans," but rather on product's intended uses as shown by the statements made in the product's labeling and advertising. *Kasz*, 855 F. Supp. at 539. This has been a bedrock principle under the FDCA since its enactment. Unfortunately, it is a concept the district court failed to grasp.

III. THE PERMANENT INJUNCTION WAS AN ABUSE OF DISCRETION

Allergan proclaims that courts "regularly" enjoin the sale of unapproved drugs. (AllBr. 45) The two cases Allergan cites for this proposition, however, were enforcement proceedings *by FDA* for violations of *federal* law. In the 75-year history of the FDCA, no court—state or federal—has ever granted a private party a nationwide injunction barring the sale of a competing product based on a

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[7] Allergan argues that the Fourth Circuit's decision in *Brown & Williamson* is irrelevant because the case concerned FDA's jurisdiction over cigarettes. The jurisdictional question, however, turned on whether cigarettes were drugs under the FDCA, which required the court to apply the intended use standard.

purported violation of one state's law. The injunction is unprecedented and must be reversed.

A. The District Court Improperly Presumed Irreparable Harm

Allergan does not dispute that, under the Supreme Court's *eBay* ruling, irreparable harm cannot be presumed. Allergan insists, however, that the district court did not presume, but rather "expressly found," irreparable harm. This is pure semantics: there is no evidence in the record that supports the "finding" of irreparable harm. A finding unsupported by evidence is, by definition, a presumption.

Allergan also cites cases recognizing that irreparable harm can be shown by proof of lost sales, prospective customers, market share, and goodwill. (AllBr. 46) But unlike Allergan, the plaintiffs in these cases offered *evidence* that they in fact had suffered such injuries. *See Douglas Dynamics, LLC v. Buyers Prods. Co.*, 2013 U.S. App. LEXIS 10155, at *15-16 (Fed. Cir. May 21, 2013) ("evidence submitted by [patentee]" established loss of goodwill); *Presidio Components, Inc. v. Am. Tech. Ceramics Corp*., 702 F.3d 1351, 1363 (Fed. Cir. 2012) (plaintiff actually demonstrated lost profits); *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1306 (Fed. Cir. 2012) (proof of "lost market share and price erosion," combined with defendant's disregard of previous injunctions, supported injunction). Allergan

submitted no comparable proof, and its authorities merely underscore the deficiency of its showing.

Allergan points to three pieces of evidence that supposedly support the finding of irreparable harm: [redacted].[8] (AllBr. 48) None of these items documents irreparable harm resulting from Athena's purportedly unlawful drug claims. At best, they show that Allergan and Athena compete, that some consumers opt for cosmetics before trying prescription drugs, and that there are reasons *unrelated* to Athena's purportedly unlawful drug claims (*e.g.*, the potential side effects of Latisse) that consumers might choose RLA instead.

In our opening brief, we showed that competition between cosmetics and drugs is perfectly lawful, and that a contrary presumption was expressly rejected in *Ortho Pharm. Corp. v. Cosprophar, Inc*., 32 F.3d 690, 695, 697 (2d Cir. 1994). Allergan's attempts to distinguish *Ortho* and show that it has no bearing on injunctions post-*eBay* are unavailing. First, Allergan notes that *Ortho* arose under

[8] Allergan repeatedly cites the district court's opinions as evidence. Opinions, however, are just that; they do not carry evidentiary weight.

the Lanham Act, whereas *eBay* was a patent case. The Ninth Circuit, however, has held that *eBay* extends beyond the patent context. *See Perfect 10, Inc. v. Google, Inc.*, 653 F.3d 976 (9th Cir. 2011) (*eBay* "overruled" the presumption of irreparable harm across the board).

Second, Allergan argues that the court of appeals "left undisturbed" the district court's "finding" in *Ortho* that a plaintiff can establish lost sales by proving that "people who buy [one] product are aware that [the other] is an option." (AllBr. 49) But the court did not deem such evidence sufficient to demonstrate irreparable harm. It merely remarked that, absent proof of such awareness, irreparable harm could not be established. *Ortho*, 32 F.3d at 695.

Allergan failed to prove that it lost sales as a result of Athena's allegedly unlawful drug claims. The district court's "finding" of irreparable harm therefore cannot stand.

B. The Injunction Is Overbroad

The district court prohibited Athena from ever selling an eyelash conditioner formulated with a prostaglandin, regardless of how the product is named, labeled or marketed. Allergan's contention that the injunction was "narrowly tailored" is facially absurd. (AllBr. 50) The specific violation alleged by Allergan was the sale of a cosmetic *with unapproved drug claims* in violation of *California* law. The nationwide injunction is not tailored to that infraction at all.

1. Allergan's Injunction Arguments Contradict Its Preemption Position

In opposing Athena's preemption argument, Allergan is adamant that it seeks to enforce only California state law, not the FDCA. (AllBr. 19) But in defending the injunction, Allergan argues that "Athena's illegal actions in this case are illegal everywhere" because the "FDCA sets a regulatory floor" throughout the country. (AllBr. 58, 60) Allergan cannot have it both ways. Sales of RLA outside California do not violate California law, so the nationwide injunction could only have been based on FDCA requirements—obligations that only FDA can enforce.

2. California's UCL Does Not Apply Extraterritorially

Allergan declares that "[n]ationwide injunctions for violation of state law are not uncommon." (AllBr. 55) In support of this assertion, Allergan cites precisely one case, decided 25 years ago. (*Id.* (citing *Carson v. Here's Johnny Portable Toilets, Inc.*, 810 F.2d 104, 105 (6th Cir. 1987)) The fact that state law has been used to justify a nationwide injunction only once in a quarter century shows that such relief is not only "uncommon," but exceedingly rare. Indeed, the case Allergan cites is *sui generis* given its unusual facts. *See Carson*, 810 F.2d at 105 (affirming nationwide injunction "for the time being" because defendant did not even operate in states where conduct was enjoined).[9]

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[9] Allergan also cites *United States v. AMC Entertainment, Inc.*, 549 F.3d 760, 771 (9th Cir. 2008), but that case involved an alleged violation of the

The California Supreme Court has held that California's UCL does not extend to "occurrences outside the state." *Sullivan v. Oracle Corp.*, 254 P.3d 237, 248 (Cal. 2011). Allergan asks this Court to recognize an exception to *Sullivan* for out-of-state conduct that causes injury in California. But *Sullivan*'s reasoning turned entirely on where the "relevant conduct occurr[ed]," not the situs of the injury. *Id.* at 248. Following *Sullivan*, courts have limited the UCL's reach to conduct occurring within California. *Gross v. Symantec Corp.*, 2012 U.S. Dist. LEXIS 107356, at *23 (N.D. Cal. July 31, 2012) ("location of the alleged conduct…controls application of the UCL, not the domicile of the plaintiff or defendant"); *Gustafson v. BAC Home Loans Servicing, LP*, 2012 U.S. Dist. LEXIS 117493, at *16-17 (C.D. Cal. Apr. 12, 2012) (UCL applies "only if the wrongful conduct…occurred inside California"); *Sajfr v. BBG Commc'ns, Inc.*, 2012 U.S. Dist. LEXIS 15198, at *15 (S.D. Cal. Jan. 10, 2012) (same). Allergan's cases purportedly establishing a situs-of-injury exception predate *Sullivan* and are no longer good law.

Moreover, even if the UCL might permit a court to enjoin out-of-state conduct that directly causes an in-state injury (such as an out-of-state bank overcharging California borrowers), Athena's sale of RLA to a resident of

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Americans with Disabilities Act, not state law. Moreover, the Ninth Circuit *vacated* the nationwide injunction.

Vermont or New York is not conduct meaningfully directed toward California just because Allergan—a non-party to the transaction—is headquartered there. If that were true, companies in California would *always* be entitled to nationwide injunctions whenever their interests are indirectly affected by out-of-state events. Such an exception would swallow the rule laid down in *Sullivan* that the reach of the UCL extends only to California's borders.

3. The Injunction Violates the Commerce Clause and Offends Comity

Allergan argues that the nationwide injunction evokes neither Commerce Clause nor comity concerns because the sale of a misbranded drug is unlawful in every state. (AllBr. 56-58) But this tautology misses the point. The fact is that RLA *does not* violate other states' laws, and it was wrong for the district court to presume otherwise.

Allergan argues that "many states" impose the same requirements as California's Health and Safety Code, and notes that states are barred from imposing requirements that differ from the FDCA. (AllBr. 58-59) Congress, however, has not mandated that all states incorporate FDCA requirements under state law, and Allergan does not dispute Athena's showing that many states, in

fact, have not done so.[10] (AthBr. 60 & n.18 (noting that 13 states have not adopted provisions regulating "new drugs"))

Moreover, even if all 50 states made a violation of the FDCA's "intended use" standard actionable under state law, it is wrong to assume that courts in every state would apply that test in the unprecedented manner that the district court did here. As Allergan acknowledges, "courts, after all, can and do apply identically worded…provisions in widely varying ways." (AllBr. 19 (citing *Smith v. Bayer Corp*., 131 S. Ct. 2368, 2377 (2011))) Courts in other states would likely conclude that, under the "intended use" standard, an eyelash product labeled with only cosmetic and no "growth" claims is not a drug. (A2879)

Allergan attempts to defend the nationwide scope of the injunction by arguing that there is no "practical way" to enjoin sales just in California. This is simply not true. In fact, Athena provided the district court with numerous

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[10] As noted in our opening brief, many states, including Tennessee, do not permit private enforcement of their mini-FDCA statutes. Allergan responds that we failed to show that Athena's conduct would in fact be lawful in Tennessee, but that, too, misses the point. A state legislature's decision to limit standing under a statute, or provide no private remedies, is itself a policy determination that other states cannot override. In fact, unlike the California court in this case, Tennessee courts recognize that claims such as Allergan's are preempted. *See Autin v. Solvay Pharms., Inc*., 2006 U.S. Dist LEXIS 19507 (W.D. Tenn. Mar. 31, 2006) (holding that plaintiff's claims under Tennessee law that "[defendant's product] cannot be sold legally because it is a new drug without FDA approval" were impliedly preempted by the FDCA).

examples of products that currently can be purchased in every state *except* California. (A2820-21, A2883-2908)

Allergan also suggests that an injunction limited to California would invite "easy evasion" because Athena purportedly continued to sell RLA in California even after it told the district court it had stopped. (AllBr. 49-50, 54-55) Allergan is referring to the fact that, after the court granted Allergan's motion for summary judgment, Athena voluntarily removed RLA from the market even before Allergan moved for injunctive relief. Allergan subsequently accused Athena of going back on its word, but this charge was baseless, and the district court never ruled on the issue. An alleged but unproven breach of a voluntary undertaking is no justification for an overbroad injunction. *See Doty v. Cnty. of Lassen*, 37 F.3d 540, 544-45 (9th Cir. 1994) ("The imposition of a remedy broader than the minimum necessary to correct a specific violation requires the violation of past court orders.").

4. The Injunction Prohibits Lawful Conduct

Were the injunction confined to California's borders, it would still be overbroad because it forbids a broad range of lawful conduct. Allergan argues that all of the conduct prohibited by the injunction is unlawful because the FDCA and California's Sherman Law ban the sale of misbranded drugs. The injunction, however, does not bar Athena from selling only products that make unapproved

drug claims. It prohibits the sale of any eyelash product that contains a prostaglandin. (A54) Contrary to the district court's assumption, the presence of a prostaglandin in an eyelash conditioner does not make it a drug, and there are innumerable ways to lawfully market such a product without FDA approval.

Allergan argues that the district court was right to bar any prostaglandin-containing eyelash product because otherwise Athena could "evade" the injunction by making "meaningless changes in its marketing." (AllBr. 50) Allergan may believe that the difference between drug claims and cosmetic claims is "meaningless," but Congress and FDA do not. An eyelash product marketed exclusively with cosmetic claims is not unlawful, and Athena cannot be permanently enjoined from engaging in lawful activity.

CONCLUSION

While "there is a first time for everything," novel rulings and never-before-seen decrees should be approached with skepticism, for "sometimes 'the most telling indication of [a] severe constitutional problem…is the lack of historical precedent' for" the judgment under review. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2586 (2012) (quoting *Free Enter. Fund v. PCAOB*, 130 S. Ct. 3138, 3159 (2010)).

The ruling below is unprecedented. Never before has a party successfully enlisted a court (state or federal) to deem a product a "drug" where FDA has not

done so—let alone to ban the sale of that product nationwide. Congress did not authorize such private action, and the Constitution's Supremacy Clause prohibits it. The judgment of the district court must be reversed.

July 11, 2013

Respectfully submitted,

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CERTIFICATE OF SERVICE
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I, Ramiro Honeywell, hereby certify that on July 11, 2013, I electronically filed the foregoing Reply Brief of Defendant-Appellant Athena Cosmetics, Inc. [Non-Confidential] with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system.

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B). The brief contains 7,000 words, as calculated by the word count of the word processing system used in preparing it, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. Cir. R. 32(b).

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